Alan Goldhammer, PhD
ASSOCIATE VICE PRESIDENT
US REGULATORY AFFAIRS

PhRMA

May 1, 2000

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
rm. 1061
Rockville, MD 20852

Re: Docket no. 99N-4783; Administrative Practices and Procedures; Good Guidance Practices; Proposed Rule; 65 Federal Register 7321; February 14, 2000

Dear Sir/Madam:

The comments on the above proposed rule are submitted on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies that are devoted to inventing medicines allowing patients to lead longer, happier, healthier and more productive lives. Investing $26 billion annually in discovering and developing new medicines, PhRMA companies are leading the way in the search for new cures.

PhRMA has long been interested in the development and issuance of guidance documents. Such documents are useful in that they allow the Agency to present its views to the regulated industry on important procedural and regulatory matters. However, it is important that the legal status and procedures for the development of such documents be clarified. In July of 1998, PhRMA submitted a series of recommendations to the FDA regarding the implementation of the Good Guidance Practices provision of the FDA Modernization Act of 1997 (section 405). This proposed rule incorporates many of our suggestions while building upon the guidance document that the FDA issued in February of 1997. PhRMA commends the FDA for the time and effort directed towards the publication of this proposed rule that clarifies the features important to PhRMA member companies.

Section V.F. notes that the Agency has been unable to publish quarterly updates to the annual list of proposed guidance documents that is published in the Federal Register as set forth in the February 1997 guidance. FDA requests comments on whether a single annual publication coupled with timely posting of new documents to the FDA Internet site is sufficient to communicate Agency activities to stakeholders. PhRMA has no objection to this change.

99N-4783 C 14

Industry's experience to date with this new guidance development process is largely positive. PhRMA looks forward to the continued collaboration with FDA on new guidances.

Sincerely,

PhRMA

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